DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Re: Docket No. 75N-183H/CP6

Dear Mr. Donegan and Dr. Sedlak:

This is in reference to your citizen petition (CP6) dated June 1, 2001, filed under Docket No. 75N-183H in the Dockets Management Branch. The petition requests that the June 17, 1994 Tentative Final Monograph for OTC Healthcare Antiseptic Drug Products (59 FR 31401) be amended to: 1) Incorporate voluntary consensus standards set by the American Society for Testing and Materials for the effectiveness testing of final formulations of OTC healthcare antiseptic drug products, 2) allow the inclusion of additional healthcare antiseptic active ingredients and combinations of generally recognized as safe and effective (Category I) active ingredients, 3) allow combinations of OTC external analgesic ingredients with a single Category I ingredient common to both the healthcare and first aid antiseptic monographs with labeling for both antimicrobial and first aid use, and 4) allow combinations of Category I healthcare antiseptic active ingredients with Category I skin protectant active ingredients with labeling consistent with both monograph.

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR 10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, agency resources and priorities permitting. See 21 CFR 10.30(e). This is to advise you, pursuant to 21 CFR 10.30(e)(2), that because of the existence of other priorities, the Agency is unable to provide a response to the petition at this time.

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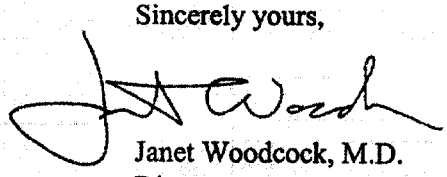
If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,



Janet Woodcock, M.D.
Director
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